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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/803,719	03/09/2001	Lewis T. Williams	2300-1624	9010

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EXAMINER
ZEMAN, MARY K

ART UNIT	PAPER NUMBER
1631	12

DATE MAILED: 10/07/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/803,719	WILLIAMS ET AL.	
	Examiner	Art Unit	
	Mary K Zeman	1631	

-- Th MAILING DATE of this communication appears on th cov r sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-15 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-15 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-8, drawn to isolated polynucleotides, vectors, transformed host cells, and recombinant methods of production, classified in class 536, subclass 23.1.

II. Claim 9, drawn to a purified polypeptide encoded by a polynucleotide from an EST library, classified in class 530, subclass 300.

III. Claim 10, drawn to an antibody to a polypeptide, classified in class 530, subclass 388.1.

IV. Claim 11, drawn to peptide-based methods of screening, classified in class 435, subclass 7.1

V. Claims 12-14, drawn to libraries of polynucleotides, classified in class 435, subclass DIG 22.

VI. Claim 15, drawn to methods of modulating gene expression, classified in class 514, subclass 44.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are separate and distinct because the inventions are directed to different chemical types regarding the critical limitations therein. For Group II, the critical feature is a polypeptide whereas for Group I the critical feature is a polynucleotide. It is acknowledged that various processing steps may cause a polypeptide of group II to be directed as to its synthesis by a polynucleotide of Group I, however, the completely separate chemical types of the inventions of Groups I and II supports the undue search burden if both were examined together. Additionally, polypeptides have been most commonly, albeit not always, separately characterized and published in the Biochemical literature, thus significantly adding to the search burden if examiner together, as compared to being searched separately. Also, it is pointed out that processing that may connect two groups does not prevent them from being viewed as distinct, because enough processing can result in producing any composition from any other composition if the processing is not so limited to additions, subtractions, enzyme actions, etc.

Inventions I and III are separate and distinct, as the claims of Invention I are drawn to polynucleotides, while the claim of group III is drawn to an antibody. These are differing

biochemical entities having differing biochemical properties, structures and effects. Invention III would require searching in areas unrelated to polynucleotides, and as such, would require an undue burden on the examiner if not restricted.

Inventions I and IV are separate and distinct as the polynucleotides of Invention I are not used in the polypeptide based screening assays of Invention IV. The two Inventions would require searching separate and non-overlapping areas which would constitute an undue search burden on the examiner if not restricted.

Inventions I and V are separate and distinct, as the polynucleotides of Invention I are to isolated, single polynucleotides, while those of Invention V are to libraries of multiple polynucleotides. Such compositions have many non-overlapping uses. The two Inventions would require searching separate and non-overlapping areas which would constitute an undue search burden on the examiner if not restricted.

Inventions I and VI are separate and distinct as the polynucleotides of Invention I are not used in the method of Invention VI. The two Inventions would require searching separate and non-overlapping areas which would constitute an undue search burden on the examiner if not restricted.

Inventions II and III are separate and distinct as the polypeptides of Invention II are structurally and biochemically different than the antibodies of Invention III. While the antibodies may bind to the polypeptides of Invention II, the biochemical activities of each Invention are quite different, requiring differing methods and areas of search, which would impose an undue burden upon the examiner.

Inventions II and IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the polypeptides can be used in expression profiles.

Inventions II and V are separate and distinct as the polypeptides of Invention II differing compositions of matter than those of Invention V. As such the Inventions would require search in separate and non-overlapping areas, imposing an undue search burned upon the examiner if not restricted.

Inventions II and VI are separate and distinct as the polypeptides of Invention II are not used in the method of Invention VI. The two Inventions would require searching separate and non-overlapping areas which would constitute an undue search burden on the examiner if not restricted.

Inventions III and IV/ VI are separate and distinct, as the antibodies of Invention III are not used in the methods of either Invention IV or Invention VI. As such the Inventions would require search in separate and non-overlapping areas, imposing an undue search burned upon the examiner if not restricted.

Inventions III and V are separate and distinct as the antibodies of Invention III are a differing composition of matter from the libraries of Invention V. As such the Inventions would require search in separate and non-overlapping areas, imposing an undue search burned upon the examiner if not restricted.

Inventions IV and VI are separate and distinct as each method comprises differing steps using differing reagents and materials, to differing ends. As such the Inventions would require search in separate and non-overlapping areas, imposing an undue search burned upon the examiner if not restricted.

Sequence Election Requirement Applicable to All Groups

In addition, each Group detailed above reads on patentably distinct Groups drawn to multiple SEQ ID Numbers. The sequences are patentably distinct because they are unrelated sequences, and a further restriction is applied to each Group. For an elected Group drawn to amino acid sequences, the Applicants must further elect a single amino acid sequence. For an elected Group drawn to nucleotide sequences, the Applicants must elect a single polynucleotide sequence.

Nucleotide sequences encoding different proteins are structurally distinct chemical compounds and are unrelated to one another. These sequences are thus deemed to normally constitute independent and distinct inventions within the meaning of 35 U.S.C. 121. Absent evidence to the contrary, each such nucleotide sequence is presumed to represent an independent and distinct invention, subject to a restriction requirement pursuant to 35 U.S.C. 121 and 37 CFR 1.141 et seq. In view of Office Resources, the search and examination of more than one sequence would pose an undue burden upon the office, therefore, Applicant must elect a single sequence to be searched. In addition to the specifically selected sequences, those sequences

which are patentably indistinct from the selected sequences will also be examined. Furthermore, nucleotide sequences encoding the same protein are not considered to be independent and distinct inventions and will continue to be examined together.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mary K Zeman whose telephone number is (703) 305-7133.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, can be reached at (703) 308-4028.

Official fax numbers for this Art Unit are: (703) 308-4242, (703) 872-9306. An *unofficial* fax number, direct to the Examiner is (703) 746 5279. Please call prior to use of this number.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the TC1600 Receptionist whose telephone number is (703) 308-0196.

mkz
10/4/02

MARY K. ZEMAN
PRIMARY EXAMINER
AU1631